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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,052	09/10/2003	Laura C. Blumberg	PC10770B	7289
28523	7590	06/06/2005	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/660,052

Applicant(s)

BLUMBERG ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/14/05 (RCE Request).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10,20 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10,20 and 22-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/05 has been entered.

Claims 10 and new 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as their invention.

1. Applicants cancellation of claim 11 and addition of claim 34 is not seen to be advancing the prosecution. It is not seen how the wordy preamble in 10 distinguishes the claim from that of 34 where the scope of active ingredient is the same.

Claims 10,20 22-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of the previous actions remain notwithstanding applicants' traverse. Contrary to what applicants urge, both

reasoning and case law have been given to support the enablement rejection. The scope is enormous easily in the billions compared to what has been made and presumably tested. Describing the invention as broadly as it is claimed does not necessarily enable one how to make and use the invention. Applicants provide no sound reasoning why one skilled in the art would expect such diverse substituted derivatives as embraced herein to behave similarly to compounds made and presumably tested, which are more similar to each other than to remaining scope as discussed in the first office action. Evidence of art-recognized biological equivalency is not seen. Literal support for the claims was also present in Surrey previously cited. If Surrey solely required literal support then the earlier Cauvallito decision (127 USPQ 202) would not have been heavily relied on as it was. Note the following quote taken from Cauvallito (regarding literal support at p.205, left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention." . With regard to structure-sensitivity note the following quote at p.206, left column: "On the other hand, wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried." . The relevant case law is not Armbruster (but note in Armbruster

additional affidavit evidence was provided) or Angstadt which both dealt with an art area other than pharmaceuticals but rather Surrey previously cited and discussed above as well as In re Fisher 166 USPQ 18 which emphasized that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” . There is no requirement that every Wands factor be deficient in order to conclude there is a lack of enablement. Applicants point to the specification for the existence of working examples- there is still none only an inference that some of the compounds were tested. Note the wording on p.46 which says: “All of the compounds **that were tested**...”.

Note MPEP 2164.08(b) which states that claims that read on “... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.” .

The fact that screening for CCR1 activity may be routine does not necessarily preclude a finding of nonenablement given the lack of any test data (just an assertion that some compounds have been tested ) and scope of claims as previously discussed. Note that in University of Rochester v. G.D.Searle & CO. 68 USPQ2d 1424 at 1438 the screening for over 600 compounds was deemed to be undue. Applicants’ scope far exceeds this number. Indeed applicants’ continued

traverse to this rejection is not consistent with their statement made in their previous response that functional groups present in applicants' compounds (vs. those in Bauman) would presumably have different pharmacological activity profiles.

The rejection over Bauman is overcome by the deletion of the R5 moiety taught by Bauman.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt  
Primary Examiner  
Art Unit 1624